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**PCT** WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/00 — A1

(11) International Publication Number: WO 97/28737

(43) International Publication Date: 14 August 1997 (14.08.97)

(21) International Application Number: PCT/FI97/00086

(22) International Filing Date: 11 February 1997 (11.02.97)

(30) Priority Data:
960637 12 February 1996 (12.02.96) FI

(71) Applicant *(for all designated States except US)*: NOKIA MOBILE PHONES LTD. [FI/FI]; Keilalahdentie 4, FIN-02150 Espoo (FI).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: HEINONEN, Pekka [FI/FI]; Hakakuja 2 B 28, FIN-02100 Espoo (FI). OKKONEN, Harri [FI/FI]; Salonkitie 5 as 3, FIN-02940 Espoo (FI).

(74) Agent: LIND, Robert; Nokia Mobile Phones Ltd., Keilalahdentie 4, FIN-02150 Espoo (FI).

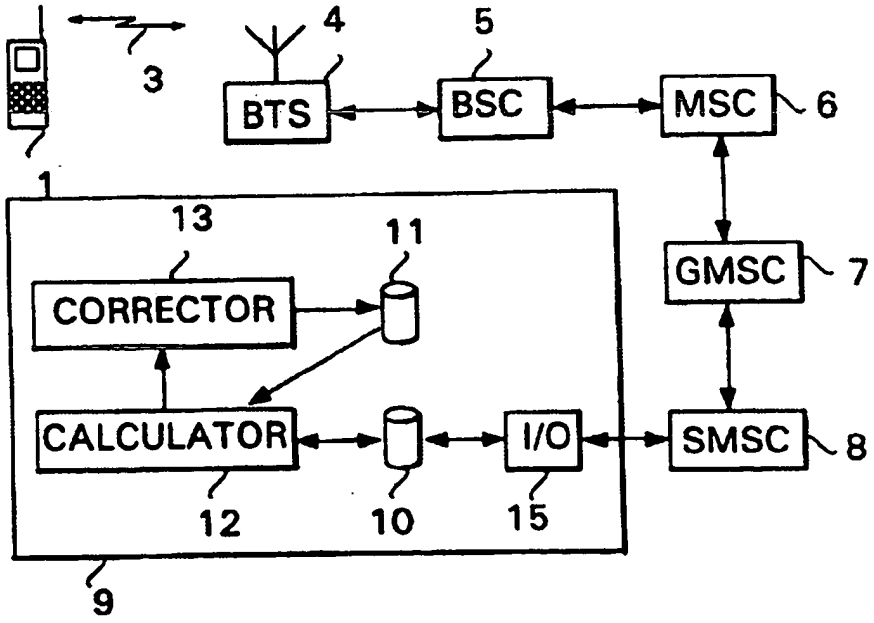
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

**Published**
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: A METHOD FOR MONITORING THE HEALTH OF A PATIENT BY MEASURING AND PREDICTING THE GLUCOSE LEVEL OF THE PATIENT'S BLOOD SAMPLE

(57) Abstract

The present invention relates to a monitoring equipment (9) comprising means (15) for receiving a measurement result indicating the patient's blood glucose level, and for storing it in a first memory means (10). In order to improve and facilitate the treatment of the patient, the monitoring equipment comprises means (15) for receiving data concerning the patient's diet, medication and physical strain, and for storing it in the first memory means (10), data processing means (11, 12) for calculating a predictive value on the basis of the data stored in the first memory means (10), and corrector means (13) for calculating the difference between the calculated predictive value and the patient's actual blood glucose level, and for correcting the mathematical model utilized to calculate the predictive value in order to take into account the aforementioned difference in subsequent calculations of predictive values.



# A METHOD FOR MONITORING THE HEALTH OF A PATIENT BY MEASURING AND PREDICTING THE GLUCOSE LEVEL OF THE PATIENT'S BLOOD SAMPLE

## FIELD OF THE INVENTION

The present invention relates to a method for monitoring the health of a patient, wherein the glucose level of the patient's blood sample is measured. The invention also relates to a monitoring equipment for monitoring the health of a patient, the equipment comprising means for receiving a measurement result indicating the glucose level in the patient's blood sample and for storing it in a first memory means together with data indicating the moment of the measurement.

## DESCRIPTION OF THE PRIOR ART

As is well known, monitoring the health of a patient with diabetes is primarily based on the measurement of the patient's blood glucose level at regular intervals. Treating diabetes requires regular measurements and regular monitoring of the measurement results in order to ensure that the patient's blood glucose level definitely remains within the allowable area and that the patient's medication is optimal.

In the present health care system it is not possible for financial and practical reasons for a person specialized in treating diabetes to personally monitor continuously the health of a patient, but the monitoring of the patient's health is largely dependent on the patient himself. Therefore the patient himself must perform measurements at regular intervals, even as often as 6 to 8 times a day. In order that the doctor treating the patient could obtain data about the development of the patient's health over a longer period, the patient must also keep a record of the measurement results, which the doctor can examine afterwards.

The fact that a relatively large number of patients with diabetes also contract a secondary disease

calculating a predictive value on the basis of the data stored in the first memory means, the predictive value indicating the patient's predictable blood glucose level at a predetermined moment, and corrector means for calculating the difference between the calculated predictive value and the patient's actual blood glucose level calculated at said predetermined moment, and for correcting the mathematical model utilized by the data processing means to calculate a predictive value in order to take into account said difference in the subsequent calculations of predictive values.

The invention is based on the idea that when an adaptive mathematical model is formulated concerning the behaviour of a patient's blood glucose level and when the patient is provided with a monitoring equipment comprising data processing means for calculating a predictive value describing the patient's blood glucose level on the basis of data supplied to the equipment, and corrector means for correcting the model used for calculating the predictive value on the basis of the difference between the previous predictive values and the actual measurement results, the patient can take care of himself better than before and monitor and predict the development of his own health, since he is able to better estimate, by means of the monitoring equipment, how his blood glucose level is likely to change on the basis of the predictable medication, diet and physical strain. In other words, if the predictive value turns out to be bad, the patient can contact for example his doctor in order to discuss possible changes in medication or he can alternatively change his diet, for instance.

Due to the corrector means the monitoring equipment becomes adaptive, i.e. it can take into account the characteristic features of the patient in question in the mathematical model utilized by the data processing

the monitoring equipment regardless of his current location. This embodiment also enables for the doctor to monitor, if desired, the most recent data concerning the patient's health without a need for an appointment, or even a phone call, between the patient and the doctor.

In another preferred embodiment of the monitoring equipment according to the invention, the monitoring equipment and the measuring equipment suitable for measuring the blood glucose level are integrated into a communications device, preferably a mobile phone, utilizing wireless data transmission. This embodiment of the invention frees the patient from carrying with him several separate conspicuous devices, since only one device is sufficient. Also in this embodiment the patient can continuously transmit, via the communications device, data concerning his health to the doctor treating him, regardless of the patient's location, and the doctor can monitor the development in the patient's health and even contact the patient directly by means of the mobile phone, if required. In this embodiment, the calculation of the predictive value is naturally not dependent on whether the patient is located in a shadow area of the mobile system at the moment, since the calculation of the predictive value takes place entirely in the monitoring equipment the patient carries with him. If the patient is in a shadow area at the moment of calculation, he can transmit afterwards, if he so wishes, the data that he has supplied to the monitoring equipment and that has been stored in the memory thereof to the data processing system available to the doctor treating him.

The preferred embodiments of the monitoring equipment according to the invention are disclosed in the appended dependent claims 3 to 7.

supplied since they may be stored in the memory of the mobile phone 1. The mobile phone 1 that is assumed to be, by way of an example, a mobile phone of the GSM mobile system (Groupe Spécial Mobile) then transmits the supplied data in the form of a short message 3 to a base station 4. The base station 4 forwards the message via a base station controller 5, a mobile services switching centre (MSC) 6 and a gateway centre 7 to a short message service centre (SMSC) 8 in the mobile system. The GSM system and the short message service thereof are described in greater detail for example in *The GSM System for Mobile Communications* by M. Mouly and M.-B. Pautet, Palaiseau, France, 1992, ISBN: 2-9507190-0-7, and therefore they will not be described in greater detail in this connection.

The short message service centre 8 is programmed to transmit the short message received from the patient's mobile phone 1 directly to the data processing system 9 of the hospital. Therefore the doctor treating the patient has at all times access to the most recent data concerning the patient, regardless of the patient's current location.

When the monitoring equipment 9 has received, via its transceiver unit 15, the data supplied by the patient, it stores it in a first memory means 10 that may consist of, for example, a file in the hard disk of a computer. A calculator 12 thereafter starts calculating a predictive value on the basis of the data stored in the first memory means. During the calculation, the calculator 12 also takes into account correction coefficients stored in a second memory means 11. The first 10 and the second 11 memory means may consist of, for example, separate storage locations situated physically in the same memory chip, or alternatively of separate files located in the same computer hard disk. The calculation of a predictive value is described in greater detail in connection with Figure 3.

means 11 from which the calculator 12 retrieves them for the next calculation of a predictive value.

If the most recent moment of measurement does not correspond to the moment for which the calculator 12 has already before calculated a predictive value, the calculator 12 first calculates a new predictive value for this moment of measurement on the basis of the data stored in the memory means 10. The corrector 13 thereafter calculates the difference between the predictive value and the measurement value and new correction coefficients in the above-described manner.

If the difference between the measurement value and the predictive value calculated for example for a certain time of day is repeatedly very close to zero in the long term (for several weeks), the monitoring equipment 9 may find that the predictive value is sufficiently accurate for the time of day. In such a case, the monitoring equipment 9 may suggest to the patient for example with a short message that there is no need to measure the blood glucose level at the aforementioned moment. Therefore, the patient can decrease the number of the daily measurements one at a time as the mathematical model proves to be sufficiently accurate, until as few as 1 or 2 measurements are required each day. This considerably facilitates the patient's daily life compared to the 6 to 8 daily measurements required at present for achieving a balance.

Figures 2 and 3 illustrate the second preferred embodiment of the monitoring equipment according to the invention. In the case shown in Figures 2 and 3, the monitoring equipment 9' is connected to a mobile phone.

The mobile phone MS may be for example a conventional GSM mobile phone the battery space of which comprises, instead of a conventional battery, a unit 14' which contains integrated both a battery and components required for calculating a predictive value, these

mathematical model known per se that can be utilized in the monitoring equipment according to the invention is a so-called Widrow's adaptive LMS (Least Means Square) algorithm.

In Figure 4, basic data $\underline{X}$ which may include data about the moment $t_i$ for which the predictive value is to be calculated, the latest measurement result, the moment of measurement, and the estimated medication, diet and physical strain of the patient is supplied to the mathematical model $\underline{H}$. The mathematical model of Figure 4 utilizes the fact that the blood glucose level of a person with diabetes usually follows a certain daily pattern with a certain accuracy, i.e. the glucose level follows the daily routine of the diabetic approximately in the same manner from one day to another. Therefore, the effect of different initial values on the glucose level can be monitored in the long term by keeping a record of the initial values and the actual measurement values. The mathematical model can therefore be amended in such a way that the model provides a more accurate predictive value. In practice, this may take place for example in such a manner that for each moment in the daily routine there is a separate correction table wherein each initial value has its own correction coefficient, i.e. for example a weighting coefficient, which is utilized when calculating a predictive value and the value of which is changed when the real difference between the calculated predictive value and the actual measurement value is known.

In the situation shown in Figure 4, a predictive value for the moment $t_i$ can be calculated for example from the formula $\hat{g}(t_i) = \underline{H} * \underline{X}$. The calculated predictive value is thereafter stored in the memory until the actual measurement value for the patient at the moment $t_i$ is obtained. When the actual measurement value $g(t_i)$ is known, the difference between the predictive value and the

Claims:

1. A method for monitoring the health of a patient, wherein the glucose level $g(t_i)$ of the patient's blood sample is measured, c h a r a c t e r i z e d by

formulating an adaptive mathematical model ($\underline{H}$) about the behaviour of the patient's blood glucose level, the model taking into account at least the patient's diet, medication and physical strain and comprising comparing the predictive values $\hat{g}(t_i)$ provided by the model to the measured glucose levels $g(t_i)$ and correcting the mathematical model ($\underline{H}$) on the basis of the result of said comparison, and

providing the patient with means (1, 9') for utilizing said mathematical model ($\underline{H}$), so that the patient can himself monitor and predict the effect of the treatment he is to follow on the behaviour of his blood glucose level.

2. A monitoring equipment (9, 9') for monitoring the health of a patient, the equipment comprising

means (15, 15') for receiving a measurement result indicating the glucose level in the patient's blood sample and for storing it in a first memory means (10, 10') together with data indicating the moment of the measurement, c h a r a c t e r i z e d in that the monitoring equipment comprises

means (15, 15') for receiving data concerning at least the patient's diet, medication and physical strain and for storing the data in the first memory means (10, 10'),

data processing means (11, 12, 11', 12') for calculating a predictive value $\hat{g}(t_i)$ on the basis of the data stored in the first memory means (10, 10'), the predictive value indicating the patient's predictable blood glucose level at a predetermined moment, and

that the monitoring equipment (9) comprises transmitter means (15) for transmitting the calculated predictive value $\hat{g}(t_i)$ to the communications device (1) available to the patient.

5. A monitoring equipment according to claim 2 or 3, characterized in that the monitoring equipment (9') comprises a measuring unit for measuring the glucose level of a patient's blood sample, and for storing the data indicating the measurement result and the moment of measurement in the first memory means (10').

6. A monitoring equipment according to claim 5, characterized in that the monitoring equipment and the measuring unit are connected to a communications device utilizing a wireless data transmission link, preferably to a mobile phone (MS) of a cellular radio system or to a two-way pager, the monitoring equipment (9') comprising means for transmitting the data stored in the first memory means (10') via said data transmission link to a data processing system that is available to a person treating the patient.

7. A monitoring equipment according to claim 6, characterized in that the monitoring equipment (9'), the measuring unit and the battery of the mobile phone are integrated into one component (14') that fits into the battery space of the mobile phone (MS).

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 97/00086

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, G06F, H04B, H04Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | DE 4221848 A1 (SALZSIEDER ECKARD ET AL.), 5 January 1994 (05.01.94), page 2, line 47 - page 3, line 22 | 1-5 |
| Y | | 6 |
| A | | 7 |
| | -- | |
| Y | Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society,Vol. 14, November 1992, (Paris, France), pages 1238-1239, E.J. Goméz et al: "A Telemedicine Distributed Decision-Support System for Diabetes Management", see section II | 6 |
| A | | 1-5,7 |
| | -- | |

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date f mailing of the internati nal search report |
|---|---|
| 8 July 1997 | 09.07.1997 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM | Authorized officer<br>Malin Keiiser |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

01/07/97

International application No.
PCT/FI 97/00086

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